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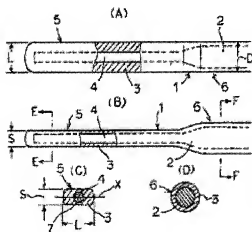
## (54) MEDICAL GUIDE WIRE AND ITS MOLDING METHOD

(57)Abstract:

**PROBLEM TO BE SOLVED:** To improve treating performance by a method wherein a tip part is formed with an irregular cross sectional shape other than a circle to bury a fine diameter part therein and a bending point is so arranged to be easily bendable only in the direction of one axis passing through the axis of a wire material for the simplification and a higher efficiency of a series of operation processes in a preparatory work for the insertion of a catheter.

**SOLUTION:** A tip part 5 with an irregular cross sectional shape of a guide wire 1 is formed with almost an evenly rectangular cross sectional shape made up of a long side L equal to the diameter D of a guide wire main part 6 and a short side S corresponding to the thickness thereof and is given a flat round- tipped shape internally existing centered on a fine diameter part 4 of a core line 2. The X axis of the center line in the direction of the long side L passing through the axis 7 of the fine diameter part 4 is plotted as neutral plane to make an

easily bendable point and a corresponding bending rigidity exists in the direction except the X axis. This facilitates the preshaping work of the tip part 5 of the guide wire to stabilize the shape quality of a crooked bend part thereby improving the workability of insertion into a blood vessel while facilitating forward guiding of the tip part 5 to a branch blood vessel.



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## DETAILED DESCRIPTION

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[Detailed Description of the Invention]

[0001]

[Field of the Invention]This invention relates to the medical-application guidewire used when introducing a catheter in a cardio-vascular system, and its forming process.

[0002]

[Description of the Prior Art]Insert the catheter of a super-thin flexible pipe object into a blood vessel for the purpose of angiography, or, Or in order to make insertion of the catheter safely reliable when inserting a balloon catheter in the therapy of the blockade part of coronary arteries into a blood vessel. The medical-application guidewire which consists of a flexible wire rod is used, and there is a well-known example of a large number shown in JP,H4-12145,B, JP,H4-20453,Y, JP,H7-7652,U, etc. And by it having the common shape of the flexible super-thin line object which can be inserted into a blood vessel, letting a catheter pass to the guidewire which carried out the insertion set into the blood vessel beforehand, and operating the guidewire as an information trunk, The insertion set of the tip of a catheter is carried out in an intravascular prescribed position, only the guidewire is drawn out and the appropriate back performs predetermined therapies, such as angiography.

[0003]Namely, since (referring to drawing 5) and the guidewire 1 are inserted in the blood vessel and branching blood vessel of a complicated course which wound from a tip and are pushed on them, Flexible flexibility and the vertical-load nature (buckling-proof nature) to a direction of movement make it required, The tip end part used as especially insertion guidance has the indispensable high flexibility and Takayoshi flexibility, and since the direction of a tip end part is controlled and insertion advance to a branching blood vessel etc. is operated, rotating the end face portion which comes out to the outside of the body moreover, the appropriate advanced mechanical properties which twist and have rigidity and steering nature simultaneously are required.

[0004]Then, the thing of JP,4-20453,Y and JP,7-7652,U of said well-known example, Make thin only the some length of the terminal of the core wire 2 of an extra fine wire, form in the thin diameter section 4, and it has the circular section shape of the diameter of uniform which embeds the overall length of the core wire 2 containing the thin diameter section 4 at the resin coating 3, The thing using a stranded wire as the core wire 2 is characterized by the structure which projects ahead only one of the strand which constitutes the stranded wire, and is embedded at the resin coating 3.

[0005]

[Problem(s) to be Solved by the Invention]The portion which was inherent in the thin diameter section 4 the thing of the above conventional structure The guidewire tip end part 5. Since it is uniform diameter circular section shape, and the flexural rigidity of the guidewire 1 becomes as uniform as all the directions, there is [ although it constitutes (it is hereafter called the tip end part 5) and has appropriate Takayoshi flexibility and high flexibility, ] fault described below.

[0006]Namely, in order to make insertion into a blood vessel easy to carry out, the Puri Shape processing which pinches and carries out plastic deformation of the tip end part 5 by a fingertip, and forms "the character curved part 8 of \*\*\*" just before insertion uses "omnidirection uniform flexural rigidity", and it bends, and is hard to bend for point absence, It is used with the shape which the curved part 8 of specified shape is difficult to get, and is against the will.

[0007]And when the tip end part 5 carries out steering operation drawn in the direction of the branching blood vessel which reaches a blood vessel branch point and should insert the curved part 8, By blood vessel internal resistance, the tip end part 5 may disturb the bending direction of the curved part 8 easily, and may make introduction to a branching blood vessel difficult, the blood vessel interpolation ON setting work of the guidewire 1 makes it complicated, trouble starts, and a patient's pain is increased.

[0008]since the stop power between strands of the thin diameter section 4 is weak, intertwinning of a strand should understand what the core wire 2 becomes from a stranded wire by crookedness of the curved part 8 -- it separates with \*\*\*\*\* 3 and there is a possibility that it may exfoliate or a strand may expose the resin coating 3. This invention provides the guidewire which cancels the difficulty of the above conventional technology, and its forming process.

[0009]

[Means for Solving the Problem]"A guidewire and a forming process of this invention which solves the above technical problem In a medical-application guidewire of a cross section circle configuration which performed resin coating to a core wire which used a long extra fine wire and used some length of a tip end part as a thin diameter section, A medical-application guidewire characterized by structure which made it easy to bend only to 1 shaft orientations which make said tip end part variant lateral cross sectional shape except circular, embed said thin diameter section, and pass along a wire rod axial center, and which bent and provided the point",

[0010]"said tip end part of a guidewire element assembly of diameter circular section shape of uniform where resin coating was performed to a core wire which used a long extra fine wire and used some length of a tip end part as a thin diameter section, It sets to a mating die for shaping which cuts a cavity of required shape and has a heating method, heating press is carried out, said tip end part is orthopedically operated to variant lateral cross sectional shape except circular, and it has become a forming process of a medical-application guidewire fabricating a guidewire of said this invention."

[0011]That is, structure which a guidewire of this invention tends to bend only 1 shaft orientations by making a front end part into the aforementioned odd shape, and secures appropriate flexural rigidity in the direction of [ other than the 1 shaft orientations ], and gives mechanical properties required for a tip end part of a guidewire is the feature. The flat shape of an approximately rectangle in which that it is circular meant a perfect circle or an approximate circle, and variant lateral cross sectional shape except circular crushed a round shape, a polygon, an ellipse form, an ellipse, etc. are meant. A core wire of a guidewire of this invention And a stranded wire of strand intertwinning besides metal single track, Or a superelastic alloy line, a shape memory alloy line, etc. are used if needed, and a thing using the stranded wire forms a thin diameter section with a stranded-wire gestalt, and a mode which provides a strand adherence part

which adhered at a tip of the thin diameter section in both strands is adopted.

[0012]

[Function] Since bending deformation can be made easy to carry out only to 1 shaft orientations and the guidewire of this invention of the above composition can make appropriate flexural rigidity exist in the direction of [ other than the 1 shaft orientations ], the tip end part used as guidance of blood vessel interpolation ON, It is easy to carry out the Puri Shape processing which forms the "character-like curved part 8 of \*\*\*" which faces blood vessel interpolation ON, and the shape and the bending direction of the curved part 8 are stabilized. And since there is no possibility of disturbing the bending direction of the curved part 8 easily and a bending direction is stabilized even if it receives the insertion resistance by the winding shape of a \*\*\*\* state or a blood vessel [ in a blood vessel ], it becomes easy to carry out introductory insertion in a branching blood vessel etc.

[0013] Since the portion by which narrow diameter processing was carried out also maintains the function as a stranded wire and stops intertwisting of a strand, the defect who produces exfoliation of resin coating and ejection exposure of a strand can prevent what adheres in both the tips of a stranded-wire strand. And it is only setting and pressing the tip end part of a guidewire element assembly to the mating die for shaping, and the guidewire of this invention can fabricate the forming process of aforementioned this invention simple and efficiently.

[0014]

[Embodiment of the Invention] Hereafter, with reference to drawing 1 in which a first embodiment of this invention is shown, it explains in detail. Namely, the guidewire 1 of this invention wraps the core wire 2 of super-thin stainless steel single track in the resin coating 3 (Nylon 12 covering etc.), uses it as a single line object, and has the circular cross section shape of the uniform diameter D. In what used as the guidewire tip end part 5 (only henceforth the tip end part 5) used as guidance of blood vessel insertion the portion in which the thin diameter section 4 which made thin only the some length of the end of the core wire 2 is inherent, The tip end part 5 is the variant lateral cross sectional shape of the approximately rectangular form which crushes the round shape of guidewire principal pieces 6 other than tip end part 5, and has the second page of parallel.

[0015] It is the flat point round shape which used uniform detailed approximately rectangle lateral cross sectional shape which consists of the long side L where the tip end part 5 of the variant lateral cross sectional shape is equal to the diameter D of the guidewire principal piece 6, and the shorter side S which hits thickness, and was inherent in the center section in the thin diameter section 4 of the core wire 2. And it has the structure of bending and making the appropriate flexural rigidity which is easy to bend the X-axis of the center line of the direction of long side L which passes along the axial center 7 of the longitudinal direction of the thin diameter section 4 as a neutral plane existing in the point in the direction of [ other than nothing and the X-axis ]. The guidewire 1 of an above drawing 1 embodiment has the aforementioned operation, make the Puri Shape processing of the tip end part 5 easy to carry out, as for it, the shape quality of "the character-like curved part 8 of \*\*\*" is stabilized, and its workability of the blood vessel interpolation ON of the guidewire 1 improves, and it becomes easy to carry out guidance advance to the branching blood vessel of the tip end part 5.

[0016] Then, the forming process of the guidewire 1 of the drawing 1 embodiment is explained based on drawing 2. That is, the guidewire element assembly 10 which performed resin coating 3 (Nylon 12 etc.) to the core wire 2 which processed the end into the thin diameter section 4 with the same technique as the thing of said well-known example is fabricated beforehand. "Then, the

end of the guidewire element assembly 10 It consists of the mating dies 11A and 11B of the up-and-down couple which cut the plastic surgery cavity 12 adjusted in the shape of the tip end part 5, And carry out a supply set at operated-orthopedically type" which has a heating method of a heater etc., and with press heating by the mating dies 11A and 11B, soften the resin coating 3, and it crushes and operates orthopedically, The guidewire 1 which wraps the tip of the thin diameter section 4 in the resin coating 3, and has the tip end part 5 of specified shape, such as said abbreviation rectangular form, is fabricated. According to the forming process of this embodiment, the guidewire 1 which has the tip end part 5 of specified shape can fabricate highly efficiently with a simple construction method.

[0017]Then, other embodiments of this invention are described with reference to drawing 3. Namely, in what has the tip end part 5 of the irregular shape cross which similarly bends the thing of this embodiment only to one axial center direction, and has the point, The publicly known stranded wire 13 which intertwisted the about 3-5 strands 14 as the core wire 2 is used, and it becomes the thin diameter section 4 reduced while the some portion of the terminal of the stranded wire 13 had been an intertwisting gestalt, and has the strand adherence part 15 to which the strand 14 at the tip of the thin diameter section 4 adhered mutually. The strand adherence part 15 of this embodiment is formed by low attachment processing by golden material or silver material.

[0018]the guidewire 1 of this drawing 3 embodiment -- the tip end part 5 -- smallness -- even if it is bent by the curvature radius or you repeat crookedness within a blood vessel, intertwisting of the strand 14 should be known -- there being very few possibilities of separating with \*\*\*\*\* 3, and, Defects, such as exfoliation of the resin coating 3, are prevented, the performance and quality of the tip end part 5 are stabilized, and the pliability and the flexible merit in which the thing of stranded-wire composition excels the single track of the diameter of the same can be enjoyed.

[0019]That is, if the stranded wire of the diameter of the same is contrasted with single track, although flexibility and rigidity will be limited in general by construction material as for single track, a stranded wire excels single track in flexibility and pliability, and a flexible and rigid variability region can set it up widely intentionally by intertwisting composition. Therefore, if a stranded wire is adopted as a guidewire core wire, the variable selected area of the mechanical properties as a guidewire becomes large, and it can be made the thing of "being high quality more." And by improvement in the blood vessel interpolation ON nature by flexible improvement of a guidewire, in order to improve the blood vessel interpolation ON nature of a guidewire, can lessen spreading of the hydrophilic polymer etc. which are given to a periphery, and. Since the concave streak by intertwisting exists in a periphery, the adhesion of a stranded-wire core wire of resin coating improves, it does not have a possibility of producing the resin exfoliation by intravascular insertion crookedness, and, as for it, the quality of a guidewire is improved and stabilized.

[0020]The guidewire 1 of this invention is not limited to the aforementioned embodiment, but the irregular shape cross shape of the tip end part 5, Make 1 shaft orientations of the X-axis into the ellipse, ellipse form, polygon, etc. which are made into a neutral plane and in which it bends and the point exists like the drawing 4 illustration, or, There is change of making plane shape of the tip end part 5 a little broader than the guidewire principal piece 6, making it the multistage shape etc. from which thickness changes to a longitudinal direction, or making the outside of the tip end part 5 continuation of taper taper shape, a taper part, and a straight part. And formation of the strand adherence part 15 may be based on the means for detachable except said.

[0021]

[Effect of the Invention] Since the Puri Shape processability which faces blood vessel interpolation ON, and the insertion nature of the guidewire of this invention into a blood vessel improve as the above explanation, Simplification promotion of efficiency of a series of operation processes of the preparatory work of the catheter implantation for angiography etc. is carried out, improvement in the therapy nature concerned is aimed at, and what consists of a core wire of stranded-wire composition prevents poor generating of exfoliation of resin coating, etc., enjoys the merit by a stranded wire, and can promote the further improvement in guidewire performance. And the forming process of the guidewire of this invention fabricates the useful guidewire efficiently, and can provide it by low cost. There are the above several effects.

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## CLAIMS

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[Claim(s)]

[Claim 1] In a medical-application guidewire of a cross section circle configuration which performed resin coating to a core wire which used a long extra fine wire and used some length of a tip end part as a thin diameter section, A medical-application guidewire characterized by structure which made it easy to bend only to 1 shaft orientations which make said tip end part variant lateral cross sectional shape except circular, embed said thin diameter section, and pass along a wire rod axial center, and which bent and provided the point.

[Claim 2] A medical-application guidewire of Claim 1 which provided a strand adherence part which a core wire consisted of stranded wires, and adhered at a tip of a thin diameter section in both the strands of said stranded wire.

[Claim 3] Said tip end part of a guidewire element assembly of diameter circular section shape of uniform where resin coating was performed to a core wire which used a long extra fine wire and used some length of a tip end part as a thin diameter section, A forming process of a medical-application guidewire setting to a mating die for shaping which cuts a cavity of required shape and has a heating method, carrying out heating press, operating said tip end part orthopedically to variant lateral cross sectional shape except circular, and fabricating a guidewire of Claim 1 or Claim 2.

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## DESCRIPTION OF DRAWINGS

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[Brief Description of the Drawings]

[Drawing 1] The tip end part of the medical-application guidewire of a first embodiment of this invention is shown, and, as for the side view and (C), in the front view and (B), EE sectional view of (B) and (D) are [ (A) ] FF sectional views of (B).

[Drawing 2] The explanatory view of the forming process of the medical-application guidewire of the drawing 1 embodiment

[Drawing 3] The transverse-plane sectional view of the tip end part of the medical-application guidewire of other embodiments of this invention

[Drawing 4] The tip end part of the medical-application guidewire of other embodiments of this invention is shown, and, as for a cross-sectional view and (E), in (A), (B), (C), and (D), the side

view (F) is the front view, respectively.

[Drawing 5] The front view of the tip end part of the conventional medical-application guidewire

[Description of Notations]

1 Medical-application guidewire

2 Core wire

3 Resin coating

4 Thin diameter section

5 Tip end part

6 Guidewire principal piece

7 Axial center

8 Curved part

10 Guidewire element assembly

11A and 11B Mating die for shaping

12 Cavity

13 Stranded wire

14 Strand

15 Strand adherence part

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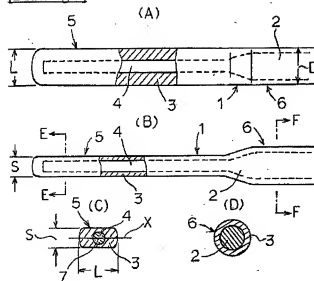
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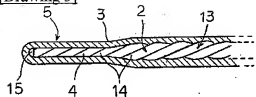
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## DRAWINGS

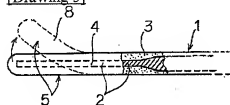
[Drawing 1]



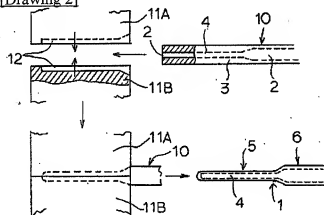
[Drawing 3]



[Drawing 5]



[Drawing 2]



[Drawing 4]

